

K080185

5.3 510(k) Summary Statement

APR 10 2008

Submitter: American Medical Systems (AMS)
10700 Bren Road West
Minnetonka, MN 55343

Contact Person: Mona Inman
Phone: 952.930.6204
Fax: 952.930.5785

Device Common Name: Surgical Mesh

Device Trade Names: AMS Elevate™ with IntePro® Lite™ Prolapse Repair System
AMS Elevate™ with InteXen® LP Prolapse Repair System

Device Classification/ Class II, 21 CFR Part 878.3300

Classification Name: Surgical Mesh, polymeric (OTP, PAI)

Predicate Device: AMS Pelvic Floor Repair System (K051485)

Indications for Use

The AMS Pelvic Floor Repair System is intended for use where the connective tissue has ruptured or for implantation to reinforce soft tissues where weakness exists in the urological, gynecological, and gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support, including urethral slings, vaginal wall prolapse repairs including anterior and posterior wall repairs, vaginal suspension, reconstruction of the pelvic floor and tissue repair.

Device Description

The AMS Elevate System is a modification of the Apogee System, part of the AMS Pelvic Floor Repair System family of devices. It consists of a permanently-implanted mesh sling assembly and non-implantable surgical instruments that can be used as aids to place the mesh sling assembly in the pelvic floor. The sling assemblies are made from polymeric mesh, or a combination of polymeric mesh and surgical mesh derived from porcine dermis.

Summary of Testing

The components of the AMS Elevate Prolapse Repair System have been tested for biocompatibility and performance requirements and found to be substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

American Medical Systems (AMS)
% Ms. Mona Inman
10700 Bren Road West
Minnetonka, MN 55343

SEP 28 2012

Re: K080185

Trade/Device Name: AMS Elevate™ with IntePro® Lite™ Prolapse Repair System
AMS Elevate™ with InteXen® LP Prolapse Repair System

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical mesh

Regulatory Class: II

Product Code: OTP, PAI

Dated: March 12, 2008

Received: March 13, 2008

Dear Ms. Inman:

This letter corrects our substantially equivalent letter of April 10, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.2 Indications for Use

Indications for Use

510(k) Number (if known): K080185

Device Names: AMS Elevate™ with IntePro® Lite™ Prolapse Repair System
AMS Elevate™ with InteXen® LP Prolapse Repair System

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
NEEDED)

Neil A.P. Cahn for mcm
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

AMS Elevate™ Prolapse System
510(k) Number _____
Special 510(k) Device Modification

K080185